



The Novel Tympanostomy U-Tube (TUT) Insertions: Preliminary Clinical Results of 132 insertions

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Abstract

Sixty-five subjects between 0.9 and 84 years old underwent 132 tympanostomy tube (TT) insertions using the novel Tympanostomy U-Tube (TUT). The follow-up of these cases concentrated on the performance and side effects of these tubes, including insertion time, crusting around the tubes, clogging, granulation formation, and residual perforation following removal/extrusion. Residual perforation occurred in 4 ears (3%). Two of these patients were noncompliant with suggested follow up and returned to clinic at 18 months post insertion. Preliminary results are compared to what is known from the literature about other TTs. Conclusions: preliminary results of the TUTs suggest an improved, long-term TT that has the qualities of easy insertion, stability, and painless removal. Painless removal via a novel deployment mechanism makes it ideal for short-term use especially in children, due to the qualities of stability, drainage patency, and decrease in lumen clogging.

Introduction

Current TTs in clinical practice have been used internationally since the 1950's. They were continuously improved but still have several persistent disadvantages. They differ from each other in expected insertion time, ability to drain middle ear secretions, ease of insertion, ease of removal, tendency to clog, granulation formation, and permanent perforation after removal or extrusion. In general, it was found that in 30% of patients treated by TTs a secondary intervention was needed due to early extrusion or persistence of otitis media longer than the mean insertion period of the common TTs [1]. The popular short or medium term TTs often fail to remain in situ until the otitis media resolves [2]. Isaacson summarizes the overview of the long-term course of OME: 'Only 30-40% of children initially treated with short-term tubes require additional tubes for otitis media [2].' Long-term TTs have higher tendency to clog, to form granulations, and to result in permanent perforation after removal/extrusion.2 Due to these failures they sometimes need to be removed or replaced earlier than planned, necessitating repeat interventions. Four percent of patients treated with the short-term TTs have premature extrusion [1], whereas 6.8% (5-10%) of them need removal under general anesthesia for

failure extrusion.2 According to the National Survey of Ambulatory Surgery, in 2006, 21,446 children underwent TT removal in the ambulatory service alone (32,214 underwent surgical removal in conjunction with other procedure) [3]. About 16.6% of the long-term treated ears end with permanent perforation [4-6] and 7% have clogging [1,4]. Drainage of pus is sometimes difficult through narrow lumen of some types of these tubes. An innovative U-shape TT (Tympanostomy U-Tube or TUT, Figure 1) has been developed to address these well-documented shortcomings. The TUT combines the advantages of previous designs with a new patented shape based on finite element analysis of pressure distribution on the tympanic membrane. Asymmetric U-shaped arms (phalanges) have been designed to displace pressure away from perforation edges to maintain vascular supply to myringotomy margins. A collapse mechanism has been developed to facilitate painless removal, and a wide conically shaped lumen allows direct visualization and micro debridement. The unique collapse mechanism contains an extraction handle and a flexible arm that allows easy painless removal. These properties enable the TUT to be inserted for the treatment of OME (otitis media with effusion) or AOM (acute otitis media). The preliminary results of these TUTs are presented hereby.



Figure 1: The Tympanostomy U-Tube (TUT) (above) and in the ear (below).

The novel tympanostomy U-Tube

A new U-shaped TT (TUT) was used in this survey. This tube combines many good qualities found separately in other TTs together with new advantages:

- a) Medical grade silicone (flexible)
- b) Transparent light blue color enables detection of clogging inside the shaft
- c) Conical shape lumen eases cleaning of clog
- d) Wide internal diameter of 1.35mm in its narrower part
- e) Anterior bold arm resists extrusion forces of the tympanic membrane
- f) Springy arms reposition the TUT automatically
- g) U-shaped arms (phalanges) designed according to finite element analysis of pressure distribution along the myringotomized tympanic membrane, displace contact with the medial aspect of the tympanic membrane away from the rim and maintain undisturbed vascular blood supply
- h) Easy insertion
- i) Novel patented collapse mechanism for painless removal by pulling the extraction handle.
- j) FDA cleared, patented.

Subjects and Methods

This is a retrospective study in a tertiary medical center. The study was approved by the medical ethics committee. A detailed follow-up on patients who underwent TUTs insertions has been

carried on with accurate follow-up, stressing the aspects of clogging, granulations, efficiency of purulent drainage, widening or creation of tympanic membrane perforation, time length of insertion and crusts around the tube. A report on patients who have long enough follow-up is presented. In this group 65 patient (132 ears) who underwent TUT insertion are included. TUTs were removed and reinserted in 5 ears of patients with Samter's disease who had extremely thick mucus. We began inserting the 'Small' size of this tube and continued with both the 'Small' and the 'Regular' size which is 15% larger and stronger than the Small size. The Small size provides a short to mid-term insertion time whereas the Regular is suitable for all indications. The Small TUT was inserted in 18 ears and the Regular in 114 ones. The patients treated suffered from otitis media with effusion (OME - 109 ears), OME with retractions (7 ears), recurrent acute otitis media (RAOM - 14 ears), and a subject who suffered from flight barotrauma (2 ears). The Regular size was used in the latter part of the study. The TUT was successfully used also for intratympanic steroids treatment in few cases, but these ears are not included in this report since they were inserted for short period. For intratympanic treatment a spinal needle could be inserted through the TUT's opening to deliver the solution. Trimming the shaft of the TUT was another way of intratympanic medication, used to instill steroid ear drops into the middle ear cavity by the patient. All the subjects underwent microscopic otoscopy in every examination, before and after surgery. Many of them were photographed in the F-U visits by an endoscopic camera. The results of these visits were statistically analyzed for multiple aspects including, in addition to the above-mentioned aspects also ease of insertion, location in the tympanic membrane, spontaneous extrusion or intended removal at the end of treatment, ease of cleaning, and painless removal. The main results are hereby presented.

Results

Number of subjects: 65. Number of ears: 132. Small TUTs: 18. Regular TUTs: 114. Evaluation of ease of insertion: insertion was easy in both sizes. In all adults the TUT was inserted in the office without any anesthesia and it was almost painless. Follow-up: maximum 3.5 years. Average: 17 months.

Insertion period

Half of the 132 TUTs (21 extruded and 43 removed) are out of the ears at the end of treatment period. The other 68 TUTs are still in the ears. The mean insertion period of the spontaneously extruded TUTs was 15 months and of the removed TUTs was 17 months. Easy removal: 43 TUTs were removed at the end of treatment (including 33 children's ears). Removal was painless in all cases, all in the office.

Complications

- a) Perforation after removal/extrusion: In 4 ears the tubes caused widening of the perforation (3%) and were removed. Two of these patients failed to appear to the follow-up and came only after repeated reminders after 1.5 years. A permanent perforation occurred in their ears. Prior to the TUT insertion one ear had thin, retracted tympanic membrane. The patients

are still under follow-up, less than 6 months after removal.

b) Granulation: were found in 10%, all responded to topical treatment within 1-3 weeks.

c) Purulent discharge: 32% of ears had one or more episodes of purulent discharge, mainly in young children, probably due to AOM condition on insertion or exposure to water months after the insertion. All the ears had no difficulty in draining pus and responded nicely to topical treatment which stopped the discharge.

d) Clogging: clogging occurred in 7 Small and 10 Regular TUTs (13%), mainly in patients with Samter's syndrome. Excluding these extraordinary cases (6 ears) the clogging rate was 10%, half of them in the Regular size. All cloggings were cleaned in the office or by various otic solutions at home. The three patients (6 ears) with Samter's syndrome, having the typical extremely thick mucus, tended to clog repeatedly. In them removal and reinsertion of TUTs after cleaning was sometimes necessary.

e) Crusts around the TUT: In 55% of the TUTs small or big crusts accumulated around the tube, especially after long term period. They could be cleaned in the office using sterile normal saline and suction/micro debridement, but in non-cooperative children normal saline drops at home helped dissolving the crusts and cleaning spontaneously or by micro debridement when necessary.

Discussion

Based on early stage results of the Small TUT we developed and preferred the Regular TUT. Although preliminary, these results show that the TUT has similar side effects to other TTs (Tables 1&2). Low tendency for perforation has been noticed (1.5% in compliant patients, 3% overall), compared to 16% of the long-term TTs.2 David: it is unclear whether the 16% rate is comparable to these tut patients at 18 mo (is 18 mo in the "long term tt" criteria? In one case a retracted, thin tympanic membrane and in two other children it was after previous TTs insertions. Failure of the children to come for follow-up visits for 1-1.5 years interval increased the probability for perforation occurrence. Thin tympanic membrane and failure of follow-up appearance are considered as risk factors for permanent perforation. It has been mentioned2 that 4-6 months intervals between follow-up visits is recommended in all TTs to minimize complications such as imminent perforations or clogging. Despite the perforations the TUT provides other qualities. Permanent perforations are considered a result of long-term implantation in the tympanic membrane and it occurs mainly in the T-tubes types.

Table 1: Comparison between TUT and average TTs data.

	Regular TUT	TT
Clogging	6% (11%*)	7%
Wide lumen	1.35mm	variable
Easy removal	painless	most need general anesthesia

*: see Samter's syndrome remarks in discussion.

Table 2: Comparison between TUT and long-term TTs performances.

	Long-term TT	TUT
Clogging	>7%	6% (11%*)
Premature extrusion	low	(low) no final data
Failure extrusion	6.80%	can be removed
Need for general anesthesia for removal	4%	non
Permanent perforation	16.60%	3% (?)
Painless removal	variable	painless

*: see Samter's syndrome remarks in discussion.

The TUT provides good drainage, easy insertion, painless removal, and easy micro debridement. The painless easy removal, when relating to the 21,446 children in the U.S. per year who needed surgical removal of TTs3 and the greater number of children (30-40%)2 who need second insertions or other modalities for the treatment of prolonged OME cases – emphasizes the importance of stability of the TUT in the ear. The excellent control on insertion time length gives the clinician complete control on the case management. According to its qualities the TUT appears to be an improved long-term as well as short-term TT, suitable for insertion in every type of middle ear ventilation/ drainage problem. It can therefore exempt the surgeon from making compromises when choosing the optimal TT. Since in many cases it is difficult to predict the time length of otitis condition, this TUT, having wide-span arms provides long insertion time and the surgeon can decide when to terminate the insertion period. Due to its collapse mechanism, it allows for a painless removal also in children (in the office), after a short (for example – after flight or intratympanic treatment) or long period. Due to the wide internal diameter (1.35mm), it can easily drain pus. The wide lumen also eases cleaning clogs and enables intratympanic administration of solutions. Regular follow-up and debridement when necessary can minimize side-effects and extend the duration of insertion as clinically indicated. The 4-6 months intervals between follow-up visits, as recommended (Isaacson2) is suitable for the TUT as well as for any other kind of TT and is highly recommended to detect and treat undesired course. According to the literature the longer the TT remains in the ear the higher the incidence of complications. Crusts accumulation, granulations, clogging and widening of perforations occurred in the poor compliance patients. Combination of well-designed and tolerated TT with short intervals follow-up can minimize these complications.

As to the patients with Samter's syndrome, they are an exception since their problem is not the typical OME that we usually see. In them, the TUTs did better than various other TTs types used before in their ears. In these cases, removal and reinsertion of the TT is sometimes essential for keeping the middle ear cavity clean for the long term. For this purpose, the TUT is the ideal tube. Excluding these cases, the clogging rate in the 'Regular' TUT was 7 of 115 TUTs – 6%. In the following tables a comparison between the TUT and the literature data on other TTs are presented.

Summary

The advantages of the TUT based on our findings can be summarized as:

- a) Clinician control of duration of insertion
- b) Good drainage due to wide lumen
- c) Decreased clogging because of a wide lumen and conical shape
- d) Easy cleaning due to the conical shape
- e) Stable tube that diminishes the need for a second intervention
- f) Easy, painless removal upon the surgeon's decision (due to the unique collapse mechanism)
- g) Low rate of perforations in our study (no final results), probably due to the novel design of the patented arched arms
- h) The TUT is suitable for repeated intratympanic administration of medication

- i) These qualities make the TUT a good choice TT for every indication.

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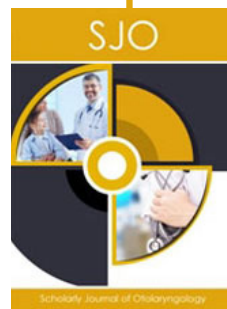
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